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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/084,837 05/26/98 LUTTICKEN

H I/97269-US

HM22/0702

EXAMINER

AKZO NOBEL N V
1300 PICCARD DRIVE SUITE 206
ROCKVILLE MD 20850-4373

MOSHER, M

ART UNIT PAPER NUMBER

1643

10

DATE MAILED:

07/02/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/084,837	Applicant(s) Lutticken et al
	Examiner Mosher	Group Art Unit 1643

Responsive to communication(s) filed on 2/10/99

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-4, 6-10, 12, 13, 15-21, and 24-31 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) 12, 13, and 16-21 is/are allowed.

Claim(s) 1, 2, 6, 7, 9, 10, 15, 24, 26, 28, 30, and 31 is/are rejected.

Claim(s) 3, 4, 8, 25, 27, and 29 is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 9

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The amended sequence listing filed 2/10/99 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the designation of "human" as the origin of the nucleic acid sequences in field <213>.

A replacement listing (both paper and CRF) is required.

Claim Rejections - 35 USC § 112

Claims 1, 2, 6, 7, 9, 10, 15, 24, 26, 28, 30, and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while containing an adequate written description and being enabling for mutant IBDV that does not produce a VP 5 protein, does not reasonably provide enablement for the full scope of mutations which render the virus "not able to produce a native VP5 protein", or reasonably convey possession of the full scope of such mutants. On reconsideration, this rejection is addressed to the independent claim 1 as well as dependent claim 2.

Applicant argues that the working examples involve substitution mutations. Although the working examples do substitute one codon for another and are thus technically substitution mutations, the working examples are not representative of the full gamut of "substitution mutations" which render a virus "not able to produce a native VP5 protein". The working examples involve two very specialized types of mutations: destruction of the translation-initiation

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codon so that VP5 is not produced at all, and chain-termination mutations so that only a few amino acids of VP5 are produced. Since such chain-termination peptides are routinely degraded rapidly by the host cell, the second type of substitution mutation also results in a virus in which VP5 is not produced at all. However, claim 2 also encompasses any and all mis-sense mutations. According to specification page 4, “not able to produce a native VP5 protein” includes “a polypeptide that can be distinguished by serological tests from the native VP5 protein.” The specification does not provide any guidance regarding the location of immunogenic epitopes in the VP5 protein, and one skilled in the art is unable to predict the structure of such epitopes or to predict the mutations which alter them. For these reasons, the specification is seen as limited to an adequate written description and enablement of mutations which result in a virus not able to produce a VP5 protein.

The above rejections could be obviated by deleting “native” from independent claim 1.

Allowable Subject Matter

Claim 12, 13, and ¹⁴ ~~17~~-21 are allowed.

Claim 3, 4, 8, 25, 27, and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1, 2, 6, 7, 9, 10, 15, 24, 26, 28, 30, and 31 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Eisenschenk, can be reached on (703) 308-0452. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196 .

June 30, 1999



MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1600
1600